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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,634	05/17/2007	Bjarne Larsen	66123US(300586)	2264
21874	7590	02/02/2010	EXAMINER	
EDWARDS ANGELL PALMER & DODGE LLP			KOSAR, ANDREW D	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/590,634

Applicant(s)

LARSEN ET AL.

Examiner

ANDREW D. KOSAR

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76, 78-80, 84-89 and 92-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76, 78-80, 84-89 and 92-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/23/06, 9/6/07, 4/16/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of SEQ ID NO:20 in the reply filed on November 18, 2009 is acknowledged. However, Applicant did not elect an invention- product or method of use, as was required (*See Election/Restriction, page 2*- "Independent claim 76..."). However, in light of the allowability of SEQ ID NO:20, indicated below, the requirement is withdrawn in the interest of compact prosecution.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 76, 78-80, 84-89, 92 and new claims 93-100 are pending and have been examined on the merits.

Allowable Subject Matter

Claim 76 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. The claim is generally drawn to peptides comprising SEQ ID NO:20. It is noted from the sequence disclosure that SEQ ID NO:23 is attached at the Lys¹⁷ in a branched manner.

Specification

The disclosure is objected to because of the following informalities: Throughout the specification, numerous compounds are misspelled, missing the terminal 'e', e.g. carboxymorpholine, piperdine, azetidine, indoline; "nipecotinic" should be spelled "nipecotic" and "isonipecotinic" should be spelled "isonipecotic".

Sequence identifiers are required for the sequences described in the table spanning pages 21-23.

Please note, the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Objections

Claims 79 and 80 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims recite no additional structural requirements to SEQ ID NO:20, reciting only functional properties of the peptide, and therefore are not further limiting.

Claims 78, 80, 85, 86, 92 and 97 are objected to because of the following informalities. The claims recite numerous typographical errors that require correction, e.g claim 78, page 5, 3rd line from bottom, in defining Z, Applicant has used zero ("0") rather than "O"; claims 80 and 94 recites "Y I" where it appears the intention is "Y1" (not the letter I, but the number one), in view

of claim 79; claim 86, 2nd line and claim 97, 3rd line, the carbonyl uses zero, rather than the letter O (“C(O)” not “C(0)”); claims 86 and 97, numerous compounds are misspelled, missing the terminal ‘e’, e.g. carboxymorpholine, piperding, azetiding, indoling; “nipecotinic” should be spelled “nipecotic” and “isonipecotinic” should be spelled “isonipecotic”.

Claims 78 and 92 recite multiple times “which is absent or wherein”, e.g. Y is a peptide of formula A⁸-A⁹-A¹⁰-A-B, which is absent or wherein. It would be more appropriate to recite: “Y is absent or a peptide of formula wherein...”

Claims 85 and 96 would more clearly recite “...wherein X is absent or the sequence set forth in SEQ ID NO:23.”

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 76, 78 and 84-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 76 is drawn to a discrete peptide sequence, and cannot be ‘and/or’ a structural/functional variant of PYY. It has a sequence that is fixed and similar to PYY and is described in the specification to be a functional variant. Thus, it is unclear how the peptide can be anything other than the structural and functional analog of PYY. It appears this language is an artifact of the original claims, which described a plurality of sequences.

Claims 78 and 92 recite:

wherein the C-terminal amino expresses a free carboxylic acid group or an amide group;

and

or a multimer and/or pharmaceutically acceptable salt thereof.

. It is unclear what limitation is intended to be after 'and', being that it is a separate line and is followed by 'or a multimer and/or pharmaceutically acceptable salt thereof.'

Furthermore, it is unclear what 'multimer' is intending to describe- the entire peptide? the portion defined by X (being the last described portion)? etc.

Additionally, the claims recite:

wherein said peptide comprises at most one disulfide bridge selected from Cys³-S-S-Cys³¹, Cys⁷-S-S-Cys²⁶, Cys⁸-S-S-Cys²⁶, and Cys⁷-S-S-Cys²⁶

, however there are no Cys at positions 24, 26, 28 or 31 of the peptide(s) of SEQ ID NO:20, thus it is unclear how one fulfills this limitation. Please note the Cys²⁴ is all caps, unlike the rest of the Cys.

Claims 78 and 92 recite "or a structure and/or functionality preserving substitution" for various amino acids. It is unclear what is a structural and/or functional substitution for each amino acid, as the specification defines these substitutions with non-limiting definitions, e.g. page 8, lines 18-25. The two definitions define the substitutions as "having similar characteristics including (size), charge, hydrophobicity, etc. such that the overall (structure) functionality of the substituted product does not change significantly." This does not define in any limiting manner what distinguishes one from the other, and does not apprise the artisan of the metes and bounds of what is/is not considered to be a structural and/or functional analog of the amino acid. Furthermore, it is unclear how one identifies a functional or structural analog of

an amino acid which is part of a peptide, where the peptide has the function, not the amino acid *per se*.

Claims 78 and 92 recite “wherein the C-terminal amino exposes a free carboxylic acid group or an amide group”. It is unclear whether it is the C-terminal amino acid, or whether Applicant intended the peptide to have a c-terminal amino group, as the claim embraces unnatural amino acids at the termini. Furthermore, it is unclear how one ‘exposes’ the amide or carboxylic acid.

Claims 84 and 95 lack clear antecedent basis, while having *ipsis verbis* support in claim 78 and 92, as discussed above there are no Cys molecules at 24, 26, 28 or 31 to cyclize the peptide.

Claims 88 and 99 lack clear antecedent basis, as claims 78 and 92 do not allow for both A and B to be Pro (A-B being a single amino acid). The claim only allows for Pro analogs having at least one additional heteroatom.

Claim 92 is drawn to a method of reducing or enhancing body weight. Enhancing is a relative term, which is not defined in the specification in a manner that would apprise the artisan of the intended meaning. The claim already has the limitation ‘reducing’, and thus it is unclear whether ‘enhancing’ is intended to mean ‘to increase’ or is synonymous with ‘reduce’, as ‘enhancing’ can be reductive perception of body weight to an obese individual or increasing body weight to an emaciated individual. Furthermore, in the context of using SEQ ID NO:20, it is unclear how the peptide can have two functions, as the sequence is indicated in the specification as being the active portion of the peptide.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654